DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 16, 2015

Ackermann Instrumente GmbH
% Mr. Frank Ferguson
Chief Executive Officer
Ferguson Medical International Device Consultants, LLC
332 Laskin Road, Suite 437
Virginia Beach, Virginia 23451

Re: K143450
Trade/Device Name: Ackermann Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 14, 2015
Received: August 17, 2015

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143450

Device Name
Ackermann Intervertebral Body Fusion Device

Indications for Use *(Describe)*
When used as a cervical intervertebral body fusion device, the Ackermann Intervertebral Body Fusion Device c|spine implants are indicated for spinal fusion procedures in skeletally mature patients. Cervical interbody fusion implants are intended for use at one level in the cervical spine, from C2 to T1, for treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment. Additionally, the c|spine implants are to be used with autogenous bone graft and supplemental fixation via an open, anterior approach.

When used as a lumbar intervertebral body fusion device, the Ackermann Intervertebral Body Fusion Device t|spine implants are indicated for spinal fusion procedures in skeletally mature patients. Lumbar interbody fusion implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for treatment of lumbar degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. The t|spine implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may be implanted via a transforaminal approach. These implants are to be used with autogenous bone graft and supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Ackermann Medical Intervertebral Body Fusion Device c|spine and t|spine implants.

DATE PREPARED: 13 August 2015

APPLICANTS NAME AND ADDRESS:

Ackermann Instrumente GmbH
Attn: Rolf Ackermann, CEO
Eisenbahnstrasse 65-67
78604 Rietheim-Weilheim
Germany
Phone: +49 7461 966170; FAX: +49 7461 9661770
RA@Ackermanninstrumente.de

APPLICANTS CONTACT PERSON IN THE USA:

Ferguson Medical International Device Consultants LLC
Attn: Frank Ferguson, CEO
332 Laskin Road
Suite 437
Virginia Beach, VA 23451
Phone: 757.286.4383; FAX: 801.749.0451
frankf@fergusonmedical-idc.com

DEVICE NAME:

Trade Name: Ackermann Intervertebral Body Fusion Device
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion Device, 21 CFR 888.3080
Product Code: MAX, ODP

LEGALLY MARKETED DEVICES TO WHICH ACKERMANN IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Primary Predicate Device: Amedica Valeo II Interbody Fusion Device (K142347)
Additional Predicate Devices: Aesculap CeSpace PEEK Spinal Implant System (K083311) and Aesculap PEEK Spinal Implant System (K071983)

DEVICE DESCRIPTION:

Ackermann Intervertebral Body Fusion Device c|spine and t|spine is an intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy. Components are manufactured from implant grade PEEK (polyetheretherketone, VESTAKEEP® i4 R by Evonik).

INTENDED USE:

When used as a cervical intervertebral body fusion device, the Ackermann Intervertebral Body Fusion Device c|spine implants are indicated for spinal fusion procedures in skeletally mature patients. Cervical interbody fusion implants are intended for use at one level in the cervical spine, from C2 to T1, for treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment. Additionally, the c|spine implants are to be used with autogenous bone graft and supplemental fixation via an open, anterior approach.

When used as a lumbar intervertebral body fusion device, the Ackermann Intervertebral Body Fusion Device t|spine implants are indicated for spinal fusion procedures in skeletally mature patients. Lumbar interbody fusion implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for treatment of lumbar degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of

the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment. The t|spine implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may be implanted via a transforaminal approach. These implants are to be used with autogenous bone graft and supplemental fixation.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE:

The components of the Ackermann Intervertebral Body Fusion Device c|spine and t|spine implants are offered in the same general range of sizes and shapes of the predicate devices. The material used for the Ackermann device is the same as that used to manufacture the reference predicate.

PERFORMANCE DATA:

The Ackermann Intervertebral Body Fusion Device c|spine implants were tested for static axial compression, dynamic axial compression, static torsion, and dynamic torsion in accordance with ASTM 2077 and for load induced subsidence in accordance with ASTM 2267. The t|spine implants were tested for static axial compression and dynamic axial compression in accordance with ASTM 2077 and for load induced subsidence in accordance with ASTM 2267.

CONCLUSIONS:

Based upon the testing and comparison to the predicate device, the Ackermann Intervertebral Body Fusion Device c|spine and t|spine implants have the same intended use and similar technological characteristics. Therefore, the device is substantially equivalent to other legally marketed devices.